Attachment 3: 510(k) Summary (per 21 CFR 807.92)

DEC 19 2012

Submitter Name and Address		
Name:	Foundry NewcoXI Inc.	
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Date Prepared:	December 3, 2012	
General Device Information		
Product Name:	Cincher-2.6 Suture Anchor	
Common Name:	Suture Anchor	
Classification:	21 CFR 888.3040 Smooth or threated metallic bone fixation fastener	
Device Class:	Class: II	
Product Code:	MBI	
Predicate Devices		
Manufacturer	Device Name	510(k) Number
Smith & Nephew, Inc.	BIORAPTOR 2.3 PK	K071586
Arthrex, Inc.	PushLock	K061863
Teleflex Medical, Inc.	Force Fiber	K063778
Description		
The Cincher-2.6 Suture Anchor consists of a PEEK polymer suture anchor preloaded with a #2 polyethylene suture, loaded on an insertion tool. The Cincher-2.6 Suture Anchor is designed to facilitate fixation of soft tissue to bone. The design allows the surgeon to adjust the suture tension on the soft tissue after insertion of the anchor into bone. The device is provided sterile.		

Intended Use (Indications)

The Cincher-2.6 Suture Anchor is intended to be used for soft tissue fixation to bone in the hip, shoulder, foot, ankle, elbow, wrist, hand, and knee. The anchor is intended for use in the following procedures:

Hip
- Hip capsule repair
  - Acetabular labrum reattachment

Shoulder
- Capsular stabilization
  - Bankart repair
  - Anterior shoulder instability
  - SLAP lesion repairs
  - Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

Foot and Ankle
- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstruction
- Bunionectomy

Elbow, Wrist and Hand
- Biceps tendon reattachment
- Ulnar or radial collateral ligament reconstructions
- Lateral epicondylitis repair
- Tennis elbow repair
- Scapholunate ligament reconstruction

Knee
- Extra-capsular repairs:
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
  - Vastus medialis obliquous advancement
- Iliotibial band tenodesis

Comparison to the Predicate Devices

The Cincher-2.6 Suture Anchor has a similar intended use and fundamental technology as the Smith & Nephew, Inc. BIORAPTOR 2.3 PK and the Arthrex, Inc. PushLock predicate devices. The technological characteristics of the Cincher-2.6 Suture Anchor are substantially equivalent to the predicate devices including biocompatibility, bench testing, packaging, sterilization, and labeling. Through bench testing it was demonstrated that the modified design do not adversely affect the safety and effectiveness.

Summary of Non-clinical and Clinical Testing

The non-clinical test data in this submission demonstrated that the Cincher-2.6 Suture Anchor meets the performance specifications. The 510(k) notice contains summaries of bench studies that were conducted to evaluate the anchor performance as specified in the FDA Guidance Document for Testing Bone Anchor Devices (dated April 20, 1996). The testing demonstrated that the Cincher-2.6 Suture Anchor meets the design specifications with respect to Static Anchor Pull Out Strength and Displacement and Pull Out Strength After Cyclic Loading.

Statement of Equivalence

The Foundry NewcoXI Cincher-2.6 Suture Anchor has a similar indications for use and technological characteristics as the predicate devices. Based on this and the data provided in this premarket notification, the Cincher-2.6 Suture Anchor and the predicate devices have been shown to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Foundry Newco Xi
% Mr. Michael Kolber
14734 La Rinconada Drive
Los Gatos, California 95032

Leter dated: December 19, 2012

Re: K122954
Trade/Device Name: Cincher-2.6 Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: September 24, 2012
Received: September 25, 2012

Dear Mr. Kolber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1: Indications for Use Statement

Indications for Use

510(k) Number (if known): K122954

Device Name: Cincher-2.6 Suture Anchor

Indications for Use: The Foundry NewcoXI Cincher-2.6 Suture Anchor is intended for the reattachment of soft tissue to bone for the following indications:

Hip
- Hip capsule repair
  - Acetabular labrum reattachment

Shoulder
- Capsular stabilization
  - Bankart repair
  - Anterior shoulder instability
  - SLAP lesion repairs
  - Capsular shift or capsulolabral reconstructions
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- Rotator cuff tear repairs
- Biceps tenodesis

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- Patellar realignment and tendon repairs
  - Vastus medialis obliquous advancement
- Iliotibial band tenodesis

The Foundry NewcoXI Cincher-2.6 Suture Anchor is intended for single-use only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey Hanley

For Division of Orthopaedic Devices